

K223068 Medical Protective Mask (model: 8862, 8862A, 8862B, 8862C, 8862D, 8862E)Nov 23, 2022
54 days to decisionK223068 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k223068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 30, 2022
Decision date	Nov 23, 2022
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Golden Leaves Technology Development Co., Ltd.
Location	Dongguan, CN
Contact	Wenhong Zhou
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , Ltd.
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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